

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI**

JAMES KELLY,

Plaintiff,

vs.

**WRIGHT MEDICAL TECHNOLOGY, INC.,
WRIGHT MEDICAL GROUP, INC. and
WRIGHT MEDICAL GROUP, N.V.,**

Defendants.

Civil Action No. 20-cv-817

COMPLAINT FOR DAMAGES

Plaintiff JAMES KELLY (“Plaintiff”) files this Complaint for Damages and Jury Trial Demand against Defendants Wright Medical Technology, Inc., a Delaware corporation, Wright Medical Group, Inc., a Delaware corporation and Wright Medical Group, N.V. a foreign corporation with its United States headquarters located at 1023 Cherry Road, Memphis, Shelby County, Tennessee, respectively show the Court the following:

NATURE OF THE ACTION

1. Defendants have known for several years that its hip replacement device – the PROFEMUR® Total Hip System with PROFEMUR® Stem (the “Stem”) and PROFEMUR® Modular Neck (the “Neck”) (collectively referred to as “the PROFEMUR® Total Hip System” or “the Device”) – was prone to fail within a few years of implantation despite the fact that hip implant devices typically last more than twenty years. The Stem and Neck of Defendants’ Device is comprised of titanium alloy, Ti6A14. Defendants have long known that the Device has a tendency to fret, corrode and fracture at the location of the highest tensile stress concentration in the Neck-Stem-body transition during even low to moderate physical activity. As a result of the Device’s

defects and Defendants' tortious acts/omissions, Plaintiff JAMES KELLY, and many other patients who received these devices, endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent more difficult revision surgery to replace the faulty Device, giving rise to more pain and suffering, prolonged recovery time, and increased risk of complications and death from surgery.

2. Plaintiff JAMES KELLY has suffered from unnecessary pain, debilitation, hospitalization, risk of death, extended hospitalization and treatments as part of the necessity to undergo a very complex revision surgery because of the catastrophic failure of Defendants' defectively designed Device.

PARTIES

3. At all relevant times hereto, Plaintiff JAMES KELLY was an adult resident and citizen of the State of Missouri, residing in Florissant, St. Louis County.

4. Defendant Wright Medical Technology, Inc. ("WMT") is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant WMT is registered to do business in the State of Illinois and Tennessee and may be served with process by serving its registered agent for service, Corporation Service Company, at 2908 Poston Avenue, Nashville, Tennessee 37203-1312.

5. Defendant WMT was, at all relevant times, engaged in the business of designing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third-parties or related entities, various prosthetic orthopedic products, including the Wright Medical Profemur® Hip products that are in issue in this civil action.

6. Defendant Wright Medical Group, Inc. (“WMG”), is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant is registered to do business in the State of Tennessee and may be served with process by serving its registered agent for service, Corporation Service Company, at 2908 Poston Avenue, Nashville, Tennessee 37203-1312.

7. In 2015, WMG merged with a foreign corporation known as Tornier N.V. and is now known as and does business in the United States as Wright Medical Group N.V. Defendant Wright Medical Group N.V. is a foreign corporation with its United States headquarters located at 1023 Cherry Road, Memphis, Shelby County, Tennessee 38117.

8. Defendant Wright Medical Group N.V. maintains and/or conducts research and development, sales, and marketing administration, and administrative activities from its location at 1023 Cherry Road, Memphis, Shelby County, Tennessee 38117.

9. Defendant Wright Medical Group N.V. is the successor corporation of WMG.

10. At all relevant times hereto, WMG, now doing business in the United States as Wright Medical Group N.V., was engaged in the business of designing, manufacturing, importing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or through third-parties or related entities, various prosthetic orthopedic products, including the Profemur hip products that are at issue in this civil action.

11. Defendants WMG, Wright Medical Group N.V., and WMT, (collectively referred to as “Defendants”, “Wright”, or “Wright Medical”) at all relevant times hereto were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers,

franchisees, or alter egos of the other and acting within the scope of this respective authority by virtue of those interrelationships.

12. In its form 10-Q, filed with the United States Securities and Exchange Commission (“SEC”) for the quarter ending on March 31, 2014, WMG represented:

On January 9, 2014, pursuant to the previously disclosed Asset Purchase Agreement, dated as of June 18, 2013 (the Purchase Agreement), by and among us, MicroPort Scientific Corporation, a corporation formed under the laws of the Cayman Islands (MicroPort), and MicroPort Medical B.V., a besloten vennootschap formed under the laws of the Netherlands, we completed our divestiture and sale of our business operations operating under the OrthoRecon operating segment (the OrthoRecon Business) to MicroPort. Pursuant to the terms of the Asset Purchase Agreement, the purchase price (as defined in the Purchase Agreement) for the OrthoRecon Business was approximately \$285 million (including an estimated working capital target adjustment), which MicroPort paid in cash.

13. The sale by WMG of the OrthoRecon operating segment included the sale to MicroPort Orthopedics, Inc. the Wright Medical Profemur hip product device line, its inventories of those products, and its manufacturing facilities for those products in Arlington, Tennessee.

14. It appears from its filings with the SEC that WMG did not leave defendant WMT the approximately \$285 million realized in the sale of its OrthoRecon operating segment, but has publicly reported that the \$285 million realized in the sale of the OrthoRecon operating segment is an asset (cash) of WMG.

15. The conduct, claims, and activities of WMG and the management and control that WMG exercised over WMT, including the sale of its OrthoRecon operating segment, and taking and treating the assets of that sale as the assets of WMG, make WMG a financially liable entity for any defects in those products, or any negligence of WMT associated with the design, manufacture, labelling, promotion, distribution, or sale of the Wright Medical Profemur hip devices.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

17. Venue is proper in this district pursuant to 28 § 1391, et seq., because a substantial part of the events giving rise to this claim occurred in Missouri and this district.

18. At all times relevant hereto, throughout the United States, Wright advertised, promoted, marketed, sold and/or distributed the defective PROFEMUR® Total Hip System that included modular necks that were distributed after December 13, 2000, and before January 1, 2014, all of the same being made of a titanium-aluminum-vanadium alloy known as Ti6Al4V.

19. In December 1999, WMT and WMG acquired Cremascoli Ortho (“Cremascoli”), a European manufacturer of artificial hip devices which had designed and manufactured artificial hips with a modular neck component since approximately 1985.

20. Pursuant to the Section 510(k) Premarket Notification Process (“510(k) Process”), on December 13, 2000, Wright received permission from the United States Food and Drug Administration (“FDA”) to distribute in the United States its PROFEMUR® Hip System.

21. The FDA never considered and approved the safety of the PROFEMUR® Total Hip System, but instead concluded only that the Device was substantially equivalent to an already legally marketed device.

22. Sometime after December 13, 2000, Wright began to manufacture, label, market, promote, distribute, and sell in the United States the Wright Medical PROFEMUR® Hip System and its components, including the PROFEMUR® modular necks.

23. The Wright Medical PROFEMUR® modular necks that were distributed after

December 13, 2000, and before February 1, 2010, were all made of a titanium-aluminum-vanadium alloy known as Ti6A14V.

24. On August 25, 2009, pursuant to a subsequent Section 510(k) Premarket Notification (No. K091423), the FDA permitted Wright to distribute and market a PROFEMUR® device manufactured from cobalt chrome alloy instead of Ti6A14V, concluding – without assessing the safety of the device – only that the cobalt chrome alloy device is “substantially equivalent” to the Ti6A14V device.

25. The Wright Medical PROFEMUR® modular necks, as promoted, marketed, distributed, and sold in the United States after December 13, 2000, for use with various Wright Medical hip systems, were manufactured in twelve models or styles, six of those twelve were generally identified by Wright as “short” necks (i.e., Catalog #s PHA0-1202, PHA0-1212, PHA0-1222, PHA0-1232, PHA0-1242, and PHA0-1252), and six identified by Wright as “long” necks (i.e., Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHA0-1254).

26. In various marketing and promotional materials published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright’s sales representatives and distributors, surgeons, patients, and the general public, Wright made the following representations, statements, claims, and guarantees about its PROFEMUR® modular necks:

The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.

[Emphasis added]

and,

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

[emphasis added]

[Wright Medical Technical Monograph MH688-102 ©2004].

27. In 2001, Wright made a design change to its PROFEMUR® necks to increase the potential range of motion.

28. In making the 2001 design change to the PROFEMUR® modular necks, Wright changed the geometry, weight, and mass of the PROFEMUR® modular necks.

29. The above-referenced modular necks “designed in 1985,” and “successfully implanted in over 50,000 patients,” and for which Wright claimed, “none of the necks has experienced a clinical failure since their inception,” were of the original design that existed prior to the 2001 design change.

30. In fact, prior to the year 2001, Wright had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe.

31. In its initial 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright did not disclose to the FDA that it had notice of clinical failures in the form of modular neck fractures that had been implanted in patients in Europe.

32. Once Wright filed its 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any

instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

33. Once Wright received permission to distribute PROFEMUR® modular necks in the United States as a result of its 510(k) Premarket Notification application, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

34. Prior to January of 2005, Wright knew or received notice of clinical failures in the form of fractures of its modular necks that had been implanted in patients in Europe.

35. Prior to April 19, 2005, Wright did not report to the FDA any of the instances it knew or received notice that a PROFEMUR® modular neck had clinically failed by the modular neck having fractured in a patient in Europe.

36. On or about April 19, 2005, Wright first reported to the FDA a PROFEMUR® modular neck clinical failure where the modular neck implanted in a patient had fractured.

37. After receiving notice of the first modular neck fracture, Wright received notice of additional modular neck clinical failures in the form of modular neck fractures.

38. The number of PROFEMUR® modular neck clinical failures in the form of modular neck fractures have continued to increase over time, and continues to increase to the present day, now numbering more than 800 such clinical failures.

39. Fractures have been reported for both the long and the short versions of the PROFEMUR® modular necks.

40. The fracture rate for PROFEMUR® long modular necks is approximately eight times the fracture rate of the PROFEMUR® short modular necks.

41. Wright did not inform U.S. orthopedic surgeons known by Wright to have

implanted the Device of any reports or concerns about fractures of its PROFEMUR® modular necks until a December 1, 2008, “Safety Alert” was sent to certain “medical professionals,” which provided, in part, “[W]e have received reports of 43 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports.”

42. At the time Wright sent its December 1, 2008, Safety Alert, Wright in fact was aware of more than 43 modular neck failures (by fracture of the modular neck).

43. In Wrights’ Instructions for Use (“IFU”) that accompanied the Device from their introduction into the United States, through 2008, if not later, Wright said that the Device was contraindicated for use in obese patients, “[W]here obesity is defined as three times normal body weight.”

44. Prior to August 2010, Wright did not include a warning, precaution, or other advisory as to the use of any of its modular necks in people who weighed more than a specifically stated weight in its IFUs distributed in the United States.

45. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in heavyweight males in its IFUs distributed in the United States.

46. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in heavy lifting in its IFUs distributed in the United States.

47. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in impact sports in its IFUs distributed in the United States.

48. Even though some Wright IFUs for Devices in use prior to August 2010 contained

a section titled, “Conditions presenting increased risk of failure include,” that section of the IFU did not state that patients weighing more than a certain weight, engaging in a high level of physical activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck.

49. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled “Warning,” and a subsection within titled “Modular Necks,” Wright did not state that patients weighing more than a certain weight, engaging in a high level of physical activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck that subsection of the IFU.

50. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled “General Product Information,” that stated, “An overweight or obese patient can produce high loads on the prostheses, which can lead to failure of the prosthesis,” and, “If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation of the device, or both,” Wright did not state that patients involved in an occupation or activity that included those activities created any higher risk of failure than would exist in any other design of artificial hip stem without a modular neck.

51. On or after August 25, 2009, Wright began distributing in the United States PROFEMUR® modular necks made of a cobalt chrome alloy.

52. PROFEMUR® modular necks distributed in the United States made of cobalt chrome are made in the same twelve sizes, versions and dimensions as the PROFEMUR® Ti6A14V modular necks.

53. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks

remain susceptible to excessive micromotion and fretting corrosion at the neck-stem junction, similar to the otherwise identical model of PROFEMUR® Ti6A14V modular necks.

54. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks continue to fail (fracture) at the neck-stem junction from cyclic loading and metal fatigue, similar to the otherwise identical model of PROFEMUR® Ti6A14V modular necks.

55. Notwithstanding Defendants' knowledge, Defendants never informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that higher weight and/or higher levels of activity may place patients at an increased risk and rate of failure due to fracture of the modular necks.

56. Notwithstanding Defendants' knowledge, Defendants never directly asked its sales representatives/distributors or surgeons in the United States to directly inform any surgeons/patients who used/received these modular necks that patients of higher weight and/or higher levels of activity may be placed at an increased risk and rate of failure due to fracture of the modular necks.

57. Patient testimonials that have from time to time appeared on the Wright website and were available to Wright sales representatives/distributors, physicians, patients and the public from 2005 to January 2014, and/or that appeared in printed materials published by Wright from 2005 to January 2014, have represented that patients who received Wright artificial hips have already returned or are about to return to such activities as running, jogging, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involves lifting and moving of heavy objects, active military duty in Iraq, karate, competitive wrestling and competitive motocross racing, among other activities.

58. Patient testimonials that have from time to time appeared on the Wright website,

and in printed materials published by Wright from 2005 to January 2014, have been from men who received the Devices and weighed in excess of 250 pounds.

59. In 2014, MicroPort Orthopedics, Inc. acquired Wright Medical's OrthoRecon Division, which was the hip division responsible for designing and selling PROFEMUR® modular necks.

60. On August 11, 2015, MicroPort Orthopedics, Inc. announced a voluntary recall of the Long 8° Varus Cobalt Chrome Modular Neck, model PHAC-1254, in the interest of "patient safety".

61. The August 11, 2015, notice issued by MicroPort Orthopedics, Inc. Chairman, Dr. Zhaohua Chang, reported that "[a]s of the date of [the] announcement, MicroPort Orthopedics [had] received 28 reports of implant failures" related to the cobalt chrome neck.

62. On September 28, 2015, the FDA issued a Class 1 hip replacement recall of the PROFEMUR® Long Cobalt Chrome neck component, and advised patients to seek immediate medical treatment if they experience a sudden onset of severe pain in their post-operative hip.

PLAINTIFF JAMES KELLY'S PROFEMUR® DEVICES

63. Plaintiff JAMES KELLY brings this product liability personal injury action as a recipient of a defective medical device, i.e., a modular prosthetic hip, designed, manufactured, and distributed by Defendants.

64. On or about February 7, 2008, Plaintiff JAMES KELLY had right total hip arthroplasty, at which time he had the Device properly implanted by Jeffrey Martin ("Dr. Martin") at Barnes-Jewish West County Hospital. Specifically, Plaintiff received the PROFEMUR® Long Neutral neck made from titanium alloy Ti6Al4V.

65. Based upon the patient population that Defendants intended the PROFEMUR® hip

systems to be implanted in and at the time Plaintiff JAMES KELLY had the Device implanted, he was an appropriate patient to be implanted with this hip system.

66. On or about April 3, 2008, Plaintiff JAMES KELLY had left total hip arthroplasty, at which time he had the Device properly implanted by Jeffrey Martin (“Dr. Martin”) at Barnes-Jewish West County Hospital. Specifically, Plaintiff received the PROFEMUR® Long Neutral neck made from titanium alloy Ti6Al4V.

67. Based upon the patient population that Defendants intended the PROFEMUR® hip systems to be implanted in and at the time Plaintiff JAMES KELLY had the Device implanted, he was an appropriate patient to be implanted with this hip system.

68. Subsequent to the date of implant, Plaintiff JAMES KELLY used his Devices in a normal and expected manner.

69. On or about July 28, 2018, the femoral neck of the Device catastrophically failed, breaking into two pieces.

70. At the time of this catastrophic failure, Plaintiff JAMES KELLY was performing a normal and expected activity of daily living.

71. On March 7, 2015, following the catastrophic failure of the device in his left hip, Plaintiff JAMES KELLY presented to the emergency room of SSM DePaul Health.

72. On March 7, 2015 Plaintiff JAMES KELLY’s fractured Device was surgically removed by Dr. Martin, at Barnes-Jewish Hospital, in a surgical procedure commonly called a “revision” of the total right arthroplasty.

73. At the time the Device was implanted in Plaintiff JAMES KELLY, it was in the same condition in all relevant respects as when it left Wright’s control.

74. The PROFEMUR® Total Hip Systems (and its components) implanted in Plaintiff

JAMES KELLY were not merchantable, but were unreasonably dangerous for their intended and/or reasonably foreseeable uses in that:

A. They were and are unreasonably dangerous as a result of one or more of a combination of the following:

(1) the neck was designed in such a manner as to be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure;

(2) the surface of the section of the neck that was inserted into the femoral stem was designed in such a manner as to increase the potential for fretting and corrosion and failure;

(3) the portion of the neck that was inserted in the femoral stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion and failure;

(4) the components were designed in such a way as to make the modular neck component susceptible to fretting and corrosion, thereby increasing the potential for failure;

(5) the components were designed in such a way as to make the modular neck component susceptible to fatigue fractures;

(6) the risk of neck fracture outweighed the utility of the Device;

(7) a reasonably prudent manufacturer or seller, given knowledge of the Device's condition, would not have marketed or sold the Device; and

(8) there may be other conditions or defects yet to be determined.

B. They were dangerous to an extent beyond which would be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(1) the ordinary consumer would not contemplate that the system would catastrophically fail within ten (10) years after implantation; and

(2) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the system catastrophically failing within ten (10) years after implantation.

75. The Device is not designed to withstand the normal activities of daily living after implantation without premature failure from fatigue fractures.

76. The Device is not designed to withstand the normal activities of daily living after implantation in active or heavier weight patients without premature failure from fatigue fractures.

77. The Device was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living.

78. The Device was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living of active or heavier weight patients.

79. The Device was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in the normal activities of daily living.

80. The Device was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in the normal activities of daily living of active or heavier weight patients.

81. The Device was not tested in design and development at the level of forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

82. The Device was not tested for the FDA section 510(k) Premarket Notification Process at the forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

83. The Device was known by Defendants to be failing from fatigue fractures of the

modular necks prior to the date of its FDA section 510(k) Premarket Notification application.

84. The Device was known by Defendants to be failing from fatigue fractures of the modular necks prior to December 13, 2000, the date it received permission from the FDA to distribute these devices in the United States.

85. The Device was known by Defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to the date of its implantation in Plaintiff JAMES KELLY.

86. The Device was known by Defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to March 7, 2015, the date it was discovered to have fractured in Plaintiff JAMES KELLY's left hip.

87. Prior to the implant of the Devices in Plaintiff JAMES KELLY, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from fatigue fractures at higher than expected rates.

88. Prior to the implant of the Devices in Plaintiff JAMES KELLY, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from fatigue fractures in high activity or heavier weight patients at higher than expected rates.

89. Prior to the sudden catastrophic failure of Plaintiff JAMES KELLY's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and catastrophically failing without warning from fatigue fractures during normal activities of daily living.

90. Prior to the sudden catastrophic failure of Plaintiff JAMES KELLY's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and

catastrophically failing without warning from fatigue fractures in high activity or heavier weight patients.

91. On or about March 7, 2015, the PROFEMUR[®] Total Hip System implanted in JAMES KELLY's left side catastrophically failed, i.e., fractured at the Neck, as a result of one or more or a combination of the foregoing unreasonably dangerous conditions.

92. As a direct and proximate result of the failure of the PROFEMUR[®] Total Hip System, Plaintiff JAMES KELLY has sustained injuries and damages including, but not limited to:

- (a) undergoing surgery to remove and replace the failed prosthesis system;
- (b) extended hospital stay;
- (c) past and future pain and anguish, both in mind and in body;
- (d) permanent physical disabilities;
- (e) permanent diminishment of his ability to participate in and enjoy the affairs of life;
- (f) medical bills associated with the replacement procedure and recovery therefrom;
- (g) future medical expenses;
- (h) loss of enjoyment of life;
- (i) loss of past and future earnings and earning capacity;
- (j) disfigurement; and
- (k) physical impairment.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF **STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN** **(As to All Defendants)**

93. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

94. Plaintiff was damaged by the defective PROFEMUR[®] Total Hip System.

95. Wright was engaged in the business of manufacturing, selling and distributing the PROFEMUR[®] Total Hip System.

96. The Wright PROFEMUR[®] Total Hip System used in Plaintiff JAMES KELLY's right hip replacement surgery was supplied in a defective condition in its design, such that it was subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure, rendering it unreasonably dangerous.

97. Wright had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the PROFEMUR[®] Total Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

98. On and prior to February 7, 2008, Wright was engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Device.

99. Wright did in fact manufacture, sell, distribute, supply and/or promote the Device to Plaintiff JAMES KELLY, his implanting physician and Barnes-Jewish Hospital. Wright expected the Device it was selling, distributing, supplying, manufacturing and/or promoting to reach, and which did in fact reach, implanting physicians and consumers in the State of Illinois, including Plaintiff JAMES KELLY, his implanting physician, and Barnes-Jewish Hospital without substantial change in the condition.

100. At the time the Device left the possession of Wright and the time the Device entered the stream of commerce, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

- (a) the Device was not reasonably safe as intended to be used;
- (b) the Device had an inadequate design for the purpose of hip replacement;
- (c) the Device contained unreasonably dangerous design defects, including an inherently unstable and defective design, (i.e. a Ti6Al4V alloy modular neck with the propensity for excessive micromotion, corrosion, fretting, and fatigue under normal and expected use), which resulted in an unreasonably high probability of early catastrophic failure by fracturing;
- (d) the Device's unstable and defective design resulted in a hip prosthesis, which had risks that exceeded the benefits of the medical device;
- (e) the Device was not appropriately or adequately tested before its distribution; and
- (f) the Device has an unreasonably high propensity for excessive micromotion, fretting corrosion, and premature fracturing under normal and expected use of the Device.

101. At the time of Defendants' initial design, manufacture, marketing and sale of the Device, a safer, feasible, alternative safer design for the Device was known and available to Wright, including, but not limited to, a monoblock prosthetic hip system that did not contain a modular neck and thus, not subject to excessive micromotion, fretting corrosion and premature failure at the neck junction.

102. At the time of and subsequent to Wright's initial design, manufacture, marketing and sale of the Device, including prior to the time of Plaintiff JAMES KELLY's initial hip implant surgery, Wright had the ability to eliminate the unsafe character of the Device without impairing its usefulness.

103. Wright's PROFEMUR® Total Hip System Devices, were, therefore, defective in design or formulation in that, when they left Wright's hands, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Device's particular design or

formulation, and/or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

104. The foreseeable risks associated with the design or formulation of the Wright PROFEMUR® Total Hip System devices include, but are not limited to, the fact that the design or formulation of the PROFEMUR® Total Hip System Devices is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

105. As a direct and proximate cause of Plaintiff JAMES KELLY's use of Wright's PROFEMUR® Total Hip System Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Wright and/or its failure to comply with federal requirements, Plaintiff JAMES KELLY has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

106. As a direct and proximate result of Wright's defective product and tortious conduct as set forth herein, Plaintiff JAMES KELLY has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

107. The PROFEMUR® Total Hip System's defective condition proximately caused Plaintiff JAMES KELLY's damages.

SECOND CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
(As to All Defendants)

108. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

109. At all times relevant hereto, Wright designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip Systems that were implanted in Plaintiff

JAMES KELLY on or about February 7, 2008 and April 3, 2008.

110. At all times relevant hereto, the PROFEMUR® Total Hip System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff JAMES KELLY and Plaintiff's physician, without a substantial change in the condition in which it was sold.

111. At all times relevant hereto, Plaintiff JAMES KELLY and Plaintiff's healthcare providers used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable purpose.

112. At all times relevant hereto, the PROFEMUR® Total Hip System was dangerous, unsafe, and defective in manufacture. Such defects included, but were not limited to an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

113. Plaintiff JAMES KELLY is informed and believes, and thereupon alleges, that the PROFEMUR® Total Hip System implanted in him was defectively manufactured because it differed from the manufacturer's design and specifications, or from typical units of the same product line.

114. As a direct, legal, proximate, and producing cause of the defective manufacture of the PROFEMUR® Total Hip System implanted in Plaintiff JAMES KELLY, Plaintiff sustained injuries as set forth above.

115. The dangerous, unsafe, and defective manufacturing of the PROFEMUR® Total Hip System implanted in Plaintiff JAMES KELLY was a substantial factor in causing Plaintiff's injuries as set forth above.

THIRD CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(As to All Defendants)

116. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

117. The PROFEMUR® Total Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical community and patients, including Plaintiff JAMES KELLY and Plaintiff's healthcare providers, to the dangerous risks associated with the PROFEMUR® Total Hip System when used for its intended and reasonably foreseeable purpose. The dangers and risks included, but were not limited to an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

118. At all times relevant hereto, Plaintiff JAMES KELLY and Plaintiff's healthcare providers used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable purpose.

119. Plaintiff and Plaintiff's healthcare providers could not have discovered any defect in the PROFEMUR® Total Hip System through the exercise of due care.

120. Defendants knew or should have known, by the use of scientific knowledge available before, at, and after the time of manufacture, distribution, and sale of the PROFEMUR® Total Hip System, of potential risks and side effects associated with the PROFEMUR® Total Hip System. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein.

121. The warnings and instructions provided with the PROFEMUR® Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the PROFEMUR®

Total Hip System, which risks were known or scientifically knowable to Defendants.

122. At all times relevant hereto, Defendants knew or should have known that the design of the PROFEMUR® Total Hip System and its warnings were likely to be dangerous when used in an intended or reasonably foreseeable manner.

123. Defendants had a continuing duty to warn the medical community and public, including Plaintiff JAMES KELLY and Plaintiff's healthcare providers, of the potential risks and increased failure rate associated with the PROFEMUR® Total Hip System.

124. As a direct, legal, proximate, and producing cause of Defendants' failure to warn, Plaintiff sustained injuries as set forth above.

125. Defendants' failure to adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip System was a substantial factor in causing Plaintiff JAMES KELLY's injuries as set forth above.

FOURTH CLAIM FOR RELIEF
NEGLIGENCE
(As to All Defendants)

126. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

127. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip System for implantation into customers, such as Plaintiff JAMES KELLY, by physicians and surgeons in the United States.

128. At all times relevant hereto, Defendants knew or should have known that the novel design of the PROFEMUR® Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the PROFEMUR® Total Hip System. A reasonable manufacturer under the same and similar circumstances would have conducted additional testing and evaluation

of the PROFEMUR® Total Hip System's safety and performance prior to placing the PROFEMUR® Total Hip System into the stream of commerce.

129. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the PROFEMUR® Total Hip System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendants chose (1) not to perform any additional testing of the PROFEMUR® Total Hip System; (2) not to investigate other potential causes of the complications; (3) not to suspend sales or distribution; and (4) not to warn physicians and patients of the PROFEMUR® Total Hip System's unreasonably high propensity for corruptions, fretting and fatigue under normal and expected used of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery and causing the damages stated herein.

130. As a direct, legal, proximate, and producing cause of Defendants' negligent design, testing, manufacturing, marketing, selling, and promoting the PROFEMUR® Total Hip System, Plaintiff suffered injuries as set forth above.

131. Defendants' negligent design, testing, manufacturing, selling, and promoting the PROFEMUR® Total Hip System, was a substantial factor in causing Plaintiff JAMES KELLY's injuries as set forth above.

FIFTH CLAIM FOR RELIEF
FRAUDULENT MISREPRESENTATION
(As to All Defendants)

132. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

133. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff JAMES KELLY, Plaintiff's healthcare providers, and/or the FDA, that the PROFEMUR® Total Hip System had been properly tested and was safe and effective for

its indicated use.

134. The representations made by Defendants to the medical and healthcare community and to Plaintiff JAMES KELLY, Plaintiff's healthcare providers, and/or the FDA, regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

135. Defendants knew or should have known that the PROFEMUR® Total Hip System had not been sufficiently tested, was defectively designed, and lacked adequate warnings and instructions.

136. Defendants knew or should have known that the PROFEMUR® Total Hip System could and would cause severe and grievous injury to users of said product, and that the PROFEMUR® Total Hip System's inherent dangers exceeded any purported, inaccurate, and/or downplayed warnings.

137. When said representations were made by Defendants, Defendants knew those representations to be false and exhibited a willful, wanton, and reckless disregard for the truth of said representations.

138. Said representations were made by Defendants with the intent to defraud and deceive Plaintiff JAMES KELLY, Plaintiff's healthcare providers, the medical community, and the general public. Defendants intended said representations to induce Plaintiff, Plaintiff's healthcare providers, the medical community and the general public, to recommend, implant, and/or purchase the PROFEMUR® Total Hip System for use as part of total hip replacement surgery. Defendants' actions evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff JAMES KELLY.

139. At all relevant times, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

140. In reliance upon Defendants' representations, Plaintiff JAMES KELLY was induced and did use the PROFEMUR® Total Hip System, thereby sustaining severe and permanent personal injuries, and is now at an increased risk of sustaining severe and permanent personal injuries in the future.

141. Defendants brought the PROFEMUR® Total Hip System to the market, and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

142. As a direct, legal, proximate, and producing cause of Defendants' false representations, Plaintiff JAMES KELLY suffered the injuries set forth herein.

SIXTH CLAIM FOR RELIEF
FRAUDULENT CONCEALMENT
(As to All Defendants)

143. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

144. Defendants knew its representations were false or recklessly disregarded the truth of said representations.

145. In representations to Plaintiff JAMES KELLY, Plaintiff's healthcare providers, and/or the FDA, Defendants omitted, concealed or suppressed material information regarding the safety and performance of the PROFEMUR® Total Hip System, including, but not limited to:

(a) An unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use for the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

(b) That the PROFEMUR® Total Hip System had an unacceptably high rate of failures requiring revision surgery;

(c) That the safety and performance of the PROFEMUR® Total Hip System was not

adequately tested and/or known by Defendants;

(d) That patients implanted with the PROFEMUR® Total Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;

(e) The PROFEMUR® Total Hip System was designed, manufactured, marketed, promoted, distributed, and sold negligently, defectively, and/or improperly; and

(f) That safer alternatives were available.

146. Defendants purposefully downplayed and understated the serious nature of the risks associated with the use of the PROFEMUR® Total Hip System in order to increase and sustain sales.

147. Defendants had sole access to material facts regarding the safety and performance of the PROFEMUR® Total Hip System. Defendants knew Plaintiff and Plaintiff's healthcare providers and/or the FDA had no way to determine the truth behind Defendants' concealment, omission, and suppression of material facts as set forth herein.

148. Plaintiff and Plaintiff's healthcare providers relied on Defendants' incomplete and inaccurate representations as to the safety and performance of the PROFEMUR® Total Hip System when selecting, recommending, and implanting the PROFEMUR® Total Hip System.

149. As a direct, legal, proximate, and producing cause of Defendants' concealment of material facts, Plaintiff JAMES KELLY has suffered injuries as set forth herein.

SEVENTH CLAIM FOR RELIEF
NEGLIGENT MISREPRESENTATION
(As to All Defendants)

150. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

151. Defendants had a duty to truthfully represent to the medical community, and to

Plaintiff JAMES KELLY, Plaintiff's healthcare providers, and the FDA, that the PROFEMUR® Total Hip System was not properly tested nor found to be safe and effective for its intended use.

152. Defendants knew or should have known that its representations regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

153. Defendants failed to exercise ordinary care in determining the truth or falsity of its representations and by misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

154. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

155. As a direct, legal, proximate, and producing cause of Defendants' concealment of material facts, Plaintiff JAMES KELLY has suffered injuries as set forth herein.

EIGHTH CLAIM FOR RELIEF
PUNITIVE DAMAGES
(As to All Defendants)

156. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-90 of this Complaint.

157. Wright knew or should have known, in light of the surrounding circumstances that its conduct would naturally and probably result in injury or damage and continued the conduct with malice or in reckless disregard of the consequences, from which malice may be inferred. Accordingly, Plaintiff JAMES KELLY is entitled to an award of punitive damages.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For a trial by jury to the full extent permitted by law;

2. For general damages for personal injuries to Plaintiff, according to proof;
3. For all past, current, and future medical and incidental expenses, according to proof;
4. For all past, current, and future lost wages according to proof;
5. For punitive and/or exemplary damages in an amount sufficient to punish Defendants and deter similar conduct in the future, according to proof;
6. For prejudgment interest, as provided by law;
7. For reasonable attorneys' fees;
8. For costs of litigation; and
9. For such other and further relief as this Court may deem just and proper.

Dated: June 22, 2020

Respectfully submitted,

/s/ Tyler Schneider

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